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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/693,243 | 10/24/2003 | Rudolf Heller | 20267 US2 | 1377 |

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| EXAMINER | |
|---|---|
| HENLEY III, RAYMOND J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/693,243 | HELLER, RUDOLF | |
| | Examiner | Art Unit | |
| | Ray Henley | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/447,872.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/24/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

**CLAIMS 1-7 ARE PRESENTED FOR EXAMINATION**

Applicant's Information Disclosure Statement filed October 24, 2003 has been received and entered into the application. As reflected by the attached, completed copies of form PTO-1449, the cited references have been considered.

***Specification***

The disclosure is objected to because of the following informality:

At page 1, lines 1-2 of section [0001], "currently pending" after "September 5, 2001" should be changed to ---now abandoned---.

Appropriate correction is required.

***Claim Rejection - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Lukas-Laskey, et al. (WO 96/24348, cited by applicant) who teach a tablet (page 7, line 19) dosage form which comprises carvedilol (page 1, line 13) in amounts which range from 3.125 to 50 mg (page 8, lines 17-19) and hydrochlorothiazide (page 6, line 11) in amounts which range from 25 to 100 mg and which and which may further contain carrier materials such as polyvinylpyrrolidone (page 7, lines 14-15), lactose (page 7, line 22) and/or magnesium stearate (page 7, line 23).

The statement in present claim 1 "such that when the tablet is solubilized, the carvedilol or pharmaceutically acceptable salt thereof and hydrochlorothiazide or a pharmaceutically acceptable salt thereof have adequate bioavailability" is deemed to be an inherent characteristic of the tablet which is taught above to be old. The properties of a composition or a compound are

inseparable. Also, "Inherent anticipation does not require that person of ordinary skill in art at relevant time would have recognized inherent disclosure." See Schering Corp. v. Geneva Pharmaceuticals Inc., 67 USPQ2d 1664 (CA FC 2003).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lukas-Laskey et al. (WO 96/24348), as above.

The difference between the above and the claimed subject matter lies in that the reference fails to highlight hydrochlorothiazide dosages of from 5 to 30 mg or a dosage of 12.5 mg. Also, the reference fails to highlight the specifically claimed excipients proportions.

However, to the skilled artisan, the claimed subject matter would have been obvious because the reference teaches at page 8, lines 27-29 that "[t]he choice of initial dosage most appropriate for the particular patient is determined by the practitioner using well-known medical principles, including, but not limited to body weight.". Also, at page 9, line 25, it is indicated that the dosage range for hydrochlorothiazide of from 25 to 100 mg is a usual adult range and would have been expected to be lower if a child or adolescent were to be treated. Also, at line 26 of the same page, it is indicated that the dosage amount may be provided as a divided dose which also allows for a dosage of hydrochlorothiazide that is consistent with the dosage amounts

presently claimed. The determination of the optimum excipients proportions would have been a matter well within the purview of the skilled artisan.

Also, even if the statement in present claim 1 "such that when the tablet is solubilized, the carvedilol or pharmaceutically acceptable salt thereof and hydrochlorothiazide or a pharmaceutically acceptable salt thereof have adequate bioavailability" is not inherent, it would have been readily obvious because the reference clearly teaches that the dosage forms are effective for administration to treat various diseases. It would logically flow that in order to be effective, the tablet, once administered, would dissolve in the patient to release the active agents and provide adequate bioavailability of the active agents such that the disease states could be effectively treated.

***Double Patenting***

Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7 and 8 of U.S. Patent No. 6,403,579 in view of Lukas-Laskey, et al. (WO 96/24348).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the statement in present claim 1 "such that when the tablet is solubilized, the carvedilol or pharmaceutically acceptable salt thereof and hydrochlorothiazide or a pharmaceutically acceptable salt thereof have adequate bioavailability" is deemed to be inherent in the patented product. Also, even not inherent it would have been readily obvious because the patent identifies the composition as being "pharmaceutically acceptable" which connotes that the active agents would be bioavailable once dissolved within the patient to whom it is administered.

Also, while the patented claims do not include the presently claimed dosage amounts, such would have been obvious in view of Lukas-Laskey et al. who teach a tablet (page 7, line 19) dosage form which comprises carvedilol (page 1, line 13) in amounts which range from 3.125 to 50 mg (page 8, lines 17-19) and hydrochlorothiazide (page 6, line 11) in amounts which range from 25 to 100 mg. and further teach at page 8, lines 27-29 that "[t]he choice of initial dosage most appropriate for the particular patient is determined by the practitioner using well-known medical principles, including, but not limited to body weight.". Also, at page 9, line 25, it is indicated that the dosage range for hydrochlorothiazide of from 25 to 100 mg is a usual adult range and would have been expected to be lower if a child or adolescent were to be treated. Also, at line 26 of the same page, it is indicated that the dosage amount may be provided as a divided dose that also allows for a dosage of hydrochlorothiazide that is consistent with the dosage amounts presently claimed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ray Henley
Primary Examiner
Art Unit 1614

Mar. 18, 2004